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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/684,016	10/10/2000	David K. Kovalic	16517.031	9497

28381 7590 12/11/2008

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EXAMINER	
ZHOU, SHUBO	
ART UNIT	**PAPER NUMBER**
1631	

MAIL DATE	DELIVERY MODE
12/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/684,016	KOVALIC ET AL.	
	Examiner	Art Unit	
	SHUBO (Joe) ZHOU	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

RCE

A request for continued examination under 37 CFR 1.114 was filed in this application after a decision by the Board of Patent Appeals and Interferences, but before the filing of a Notice of Appeal to the Court of Appeals for the Federal Circuit or the commencement of a civil action. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 11/20/08 has been entered.

Claims 11-16 are presently pending and under consideration.

Claim Rejections-35 USC § 101 and § 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 11-16 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

This rejection is reiterated from the previous Office actions. It is noted that the Board affirmed the rejections in the decision mailed 9/24/08. The rejections are

reiterated below also for the reasons set forth in the Board's decision. Specifically, the specification never connects the nucleic acid of SEQ ID NO:48411 to any particular or specific utility. See pages 5-6 of the Board's decision mailed 9/24/08.

Claims 11-16 are drawn to a nucleic acid comprising a fragment nucleic acid having from about 30 to about 50 nucleotides, or from 50 to about 100 nucleotide residues of a nucleic acid having the sequence of SEQ ID NO:48411, or having between 90% and 100% identify with nucleotides 1-123 of SEQ ID NO:48411.

The claimed nucleic acids are not supported by a specific asserted utility because the disclosed uses of these nucleic acids are not specific and are generally applicable to any nucleic acid. The specification states that the nucleic acid compounds can be used in isolating more genes and homologs from plants, such as maize, etc. (see pages 37-38). All these possible uses are generic to any expressed nucleic acid sequences from plants. As a matter of fact, the specification summarized pretty much the modern biotechnology in general, but never connects any of the specifically elected sequence to any particular or specific utility. This wishlist-like desire for a utility for the claimed sequences seems to fall short of a readily available utility. Recently, in *In re Fisher,* a case analogous to the present application, the court held that an asserted use must also show that the claimed invention can be used to provide a well-defined and particular benefit to the public" and that "Fisher's claimed uses are nothing more than a 'laundry list' of research plans, each general and speculative ... ." *In re Fisher*, 76 USPQ2d 1225 1229 1230 (CAFC 2005). In the instant application, applicant does not assert a particular and well-defined benefit to the public for the claimed nucleic acids.

Further, the claimed nucleic acid is not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. For example, in the aforementioned uses in isolating new genes in plants. Further research is clearly needed to isolate the gene, to isolated the protein, if any, encoded by the gene, and to study the function/activity of the protein in order to find uses for that gene and that protein. This apparent need for such research indicates that the nucleic acid is not disclosed as to a currently available or substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case none of the proteins that are to be produced as final products resulting from processes involving claimed nucleic acid have asserted or identified specific and substantial utilities. Identifying and studying the properties of a protein itself or the mechanisms in which the protein is involved does not define a "real world" context for use. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Also in In re Fisher, the court, following an analysis of Nelson, 626 F.2d at 856, with regard to substantial utility, states that “it thus is clear that an application must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research.” In re Fisher, 76 USPQ2d 1225 1230 (CAFC 2005). In the instant case, the application does not show that the claimed polynucleotide is useful to the

public as disclosed in its current form, but that it may prove useful at some future date after further research.

Additionally, neither the specification as filed nor any art of record discloses or suggests any property or activity for the polypeptide encoded by SEQ ID NO:48411 such that another non-asserted utility would be well established for the polynucleotide encoding the polypeptide.

The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-16 are rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention lacks a patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Applicant's arguments filed 11/20/08 have been fully considered but they are not persuasive.

Applicant argues on page 3 of the response:

> The specification as filed discloses that SEQ ID NO: 48411 has significant homology to the sequence disclosed in NCBI record CAA18117, which is associated with the sequence identifier "3046693" *(i.e.,* gi:3046693).1 A review of that record indicates that the source of the sequence (DBSOURCE) is "embl accession AL022140.1". An examination of the record AL022140 indicates that the sequence associated with the identifiers CAA18117 and gi:3046693 has "strong similarity to ES43 protein..." of Barley *(H. vulgare).* Applicants respectfully submit that a skilled artisan would understand that barley ES43 protein is recognized in the art as a barley steroid hormone receptor. *See, e.g.,* NCBI record X77575 and Speulman and Salamini, A *barley cDNA clone with homology to the DNA-binding domain of the steroid receptor,* Plant Sci. 106, 91-98 (1995).[2]

Unfortunately, applicant did not particularly point out the specific section of the specification that discloses the "significant homology" of SEQ ID NO:48411 to the sequence of NCBI record CAA18117. Given that the specification encompasses thousands of pages, the Office was not able to find such disclosure. However, even if the specification does make such disclosure, One skilled in the art would have reasonable doubt that the nucleotide sequence of SEQ ID NO:48411 or fragment thereof as claimed indeed encodes a steroid hormone receptor for the following reasons:

Firstly, since the Office could not find among thousands of pages of the specification the disclosure of this "significant homology" between the two sequences, it is unclear as to the exact percentage of the homology between SEQ ID NO:48411 and CAA18117, and thus not clear how significant the homology is.

Secondly, CAA18117 was first seen in the NCBI database on 4/15/1998 and there has been at least 11 revisions thereafter. See the attached revision history of CAA18117, printed from http://www.ncbi.nlm.nih.gov/entrez/sutils/girevhist.cgi?val=CAA18117 on 12/8/08. A review of the version immediately before the filing of the instant application, i.e. the version of March 10, 2000 (see attached) reveals that CAA18117 was a direct submission to the GenBank, and the disclosure only indicates that CAA18117 is a "receptor like protein (fragment)" and has "strong similarity to ES43 protein, barley" without any supporting data. It appears that it is purely based on sequence data comparison. The disclosure did not point out, and applicant did not provide evidence to show, how "strong" the similarity is in terms of percentage of identity.

Thirdly, with regard to applicant's assertion that "a skilled artisan would understand that barley ES43 protein is recognized in the art as a barley steroid hormone receptor, applicant points to NCBI record X77575 and Speulman and Salamini, A *barley cDNA clone with homology to the DNA-binding domain of the steroid receptor,* Plant Sci. 106, 91-98 (1995). It is noted that Speulman et al. disclose in the Plant Science publication that the ES43 cDNA was isolated using oligonucleotides corresponding to a DNA-binding domain of steroid hormone receptors, and the ES43 sequence "shows homology to the DNA-binding domain of the estrogen receptor." See Abstract. However, Speulman et al. do not present any evidence as to whether ES43 encodes a steroid hormone receptor activity or estrogen receptor activity. Speulman et al. disclose the apparent discremancies between ES43 and steroid hormone receptors. See page 96, right column. Additionally, Speulman et al. point out that ES43 contains cysteine rich repeats that function as ligand binding domains found in several receptors not related to the steroid receptors, i.e. the LDL receptor. See page 97, right column.

Therefore, assuming arguento that the sequence of SEQ ID NO:48411 does have significant homology with CAA18117, which does have strong homology with ES43, one of skilled in the art would have to perform extensive further research to determine what, if any, protein(s) or hormones it may bind to, and what, if any, practical utility the binding may present.

Withdrawn rejections

The rejection of claims 11-16 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement set forth in the

previous Office action is withdrawn in view of the Board's decision mailed 9/24/08.

The rejection of claim 13 under 35 U.S.C. § 102(b) as being anticipated by Mahairas et al. is withdrawn in view of the amendment to the claim filed 11/20/08.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Shubo (Joe) Zhou/

SHUBO (JOE) ZHOU, PH.D.

PRIMARY EXAMINER